REMARKS

The only issues outstanding in the Office Action mailed December 3, 2002, are the requirement for restriction and the rejections under 35 U.S.C. §112. The Examiner is thanked for indicating that no art rejections remain. It is respectfully submitted that, in view of the following discussion, the remaining issues should be resolved. With respect to the requirement for restriction, it is noted that Applicants have petitioned this requirement concurrently with the present response.

Claim 22 has been objected to as depending on a non-elected claim. It is submitted, that on the one hand, if a claim depends on a non-elected claim, that claim itself must be non-elected. In any event, in view of the concurrently filed petitioned of the restriction requirement, it is submitted that no change to the claim is needed.

Rejections Under 35 U.S.C. §112

Claims 1, 2, 5, 8-18, 22-25 and 39 have been rejected under 35 U.S.C. §112, second paragraph. Reconsideration of this rejection is respectfully requested.

In response to the Examiner's request at page 3, the dependent claims have been amended to recite "the" process. The scope of the claims have not been changed by this amendment.

It is argued, at page 3 of the Office Action, that claims 1 and 2 lack a "determination" step. This is respectfully submitted to be in error. Claim 1 recites "determining" remanence magnetization. Thus, a determination step is present. Claim 2 recites "measuring" remanent

magnetization, and thus also, in essence, contains a determining step. It is further argued in this portion of the rejection that the claims lack a positive recitation of a contact step between reagents and sample. It is submitted that such is not necessary. Claims 1 and 2 are directed to the step of the invention involving determining remanence magnetization of a ferromagnetic or ferromagnetic substance, bound to an analyte. As discussed fully in the specification, such a step enables determination of the presence of the analyte, inasmuch as the unbound magnetic markers fade, that is, do not exhibit remanence magnetization. Thus, the step can be conducted without separation of these unbound markers, which is a significant advance over the art, as discussed in previous responses. However, it can be seen that all that is necessary to practice the invention is recited in the claim: determining remanence magnetization, in the homogeneous immunoassay, of the magnetic substance which is bound to the analyte. The analyte and magnetic substance are previously bound, and thus a contact step is neither necessary nor desired in this claim. The claim is complete as is.

It is further argued at page 3 of the Office Action that there is no positive recitation of a correlation step, that relates the remanence magnetization to the presence of analyte. Again, it is submitted that such is not necessary. If the remanence magnetization is measured, the analyte is present, inasmuch as the magnetic substance is bound thereto. This would be apparent, without any explanation, to one of ordinary skill in the art reading the present claims. While the Office Action argues that it is unclear as to "what is being detected" to determine the presence of the analyte, the claims clearly recite determining remanence magnetization and/or measuring remanence magnetization. Thus, while the Office Action argues that this has "no association with the presence of analytes," it is submitted that this statement clearly reflects a fundamental

misunderstanding of the nature of the invention which misunderstanding is likely at the root of the failure to withdraw the restriction requirement, as discussed in the separate petition. Briefly put, it is the determination of remanence magnetization of markers bound to the analyte which enables detection of the presence of the analyte. Nothing more need be said. As for whether a rise or drop in magnetization is detected, again, it is simply the presence of the magnetization which signifies the presence of the analyte. Attention is directed to the paragraph at the top of page 6 of the specification, which explains this phenomenon. It is submitted that a careful reading of this paragraph highlights the clarity of these two claims.

It is further argued, at page 3 of the Office Action, that is unclear in claim 8 how the sample is moved during measurement. The Examiner speculates that physical movement is intended (see page 4 of the Office Action) since the present specification, at page 8, discloses that the sample "can advantageously be moved. Especially advantageous is modulation of the signal by vibration or rotation of the sample." It is submitted that Applicants do not intend to limit this claim to vibration or rotation of the sample, nor to any particular form of movement. Indeed, it is not necessary to limit the claims to the particular form of movement of the sample disclosed in the specification. Since the claim is as broad as the specification (which clearly does not exempt any form of movement) and since one of ordinary skill in the art would clearly understand that any method of physically moving the sample is appropriate and included, the claim is sufficiently clear and no change therein is needed. The Examiner has not provided any evidence suggesting Applicants do not intend to include any form of movement, or that any form of movement which one of ordinary skill in the art would understand to be included in the claim would not work. Consequently, the claim is clearly definite. While Applicants agree that limitations in the

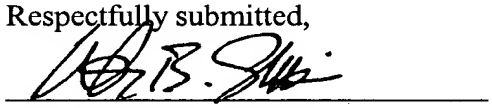
specification are not read into the claims, it is not seen that any limitation needs to be read in, since any movement of the sample falls within the scope of the claims and would be understood by one of ordinary skill in the art to be so included. Of course, a claim need not exclude embodiments which one of ordinary skill in the art would clearly understand to be impossible. See *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976).

In conclusion, it is submitted that the claims are completely clear, fully definite, and unequivocably satisfy the requirement of 35 U.S.C. §112. Withdrawal of the rejection is therefore respectfully requested.

The claims of the application are submitted to be in condition for allowance. However, should the Examiner have any questions or comments, he or she is cordially invited to contact the undersigned at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 5-8, 11-12, 16-18, 26-28, and 39-42 as follows:

5. **(Amended)** ~~A~~ The process according to claim 40, wherein the structure-specific substances are antibodies, antibody fragments, biotin, substances that bind specifically to biotin, agonists that bind specifically to receptors of their antagonists, peptides, proteins, receptors, enzyme substrates, nucleotides, ribonucleic, acids, deoxyribonucleic acids, carbohydrates, or lipoproteins.

6. **(Thrice Amended)** ~~A~~ The process according to claim 3, wherein the structure-specific substances have a binding constant in the range of 10^5-10^{15} $(mol/l)^{-1}$.

7. **(Thrice Amended)** ~~A~~ The process according to claim 3, wherein the structure-specific substances have a binding constant in the range of 10^7-10^{15} $(mol/l)^{-1}$.

8. **(Thrice Amended)** ~~A~~ The process according to claim1, wherein the sample is moved during the measurement and a sample signal is modulated.

11. **(Trice Amended)** ~~A~~ The process according to claim 1, wherein simultaneous determination of several different analytes in a sample of liquids or solid substances is carried out by sequential magnetization of a sample to be measured.

12. **(Twice Amended)** ~~A~~ The process according to claim 11, wherein for simultaneous

quantitative determination of analytes, different ferromagnetic or ferrimagnetic substances with discrete coercive field intensities are used.

16. **(Thrice Amended)** ~~A~~ The process according to claim 1, wherein the ferromagnetic and ferrimagnetic substances have a particle size of 1 to 1000 nm.

17. **(Thrice Amended)** ~~A~~ The process according to claim 1, wherein the ferromagnetic and ferrimagnetic substances have a particle size in the range of 2 to 500 nm.

18. **(Thrice Amended)** ~~A~~ The process according to claim 1, wherein the ferromagnetic and ferrimagnetic substances are stabilized with a shell of oligomeric or polymeric carbohydrates, proteins, peptides, nucleotides, surfactants, synthetic polymers, and/or lipids.

26. **(Twice Amended)** ~~A~~ The process according to claim 1, wherein ferromagnetic or ferromagnetic substances are introduced into the human body or are applied on the human body, and the remanence of the magnetization of the ferromagnetic or ferromagnetic substances is determined after a magnetizing field is shut off.

27. **(Twice Amended)** ~~A~~ The process according to claim 3, wherein ferromagnetic or ferromagnetic substances are introduced into an organism or applied on the organism, by a process comprising

(i) labeling structure-specific substances with ferromagnetic or ferromagnetic substances,

(ii) adding said magnetic labeled structure-specific substances to a living organism or applied to an organism,

(iii) magnetizing a volume of the organism with the aid of a magnetic

field that is applied from the outside and,

(iv) measuring remanence of the magnetic markers with the aid of magnetic field sensors after the external field is shut off.

28. **(Twice Amended)** ~~A~~ The process according to claim 27, wherein antibodies, antibody fragments, agonists that bind specifically to receptors or their antagonists, peptides, proteins, receptors, enzymes, enzyme substrates, nucleotides, ribonucleic acids, deoxyribonucleic acids, carbohydrates, or lipoproteins are used as structure-specific substances.

39. **(Twice Amended)** ~~A~~ The process according to claim 1, wherein the ferromagnetic or ferromagnetic substance is magnetic-labeled anticollagen II and SQUID(s) are used to determine remanent magnetization.

40. **(Amended)** ~~A~~ The process according to claim 1, wherein structure specific substances are labeled with the ferromagnetic or ferrimagnetic substances, and added to the analyte.

41. **(Amended)** ~~A~~ The process according to claim 1, wherein the analyte is labeled with structure specific substances, and the ferromagnetic or ferrimagnetic substances are added thereto.

42. **(Amended)** ~~A~~ The process according to claim 41, wherein the structure-specific substances are antibodies, antibody fragments, biotin, substances that bind specifically to biotin, agonists that bind specifically to receptors of their antagonists, peptides, proteins, receptors, enzyme substrates, nucleotides, ribonucleic, acids, deoxyribonucleic acids, carbohydrates, or lipoproteins.